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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,362	06/25/2001	George M. Grass	109904-00028	6261

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EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,362	GRASS ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-18* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 12 January 2007, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3 and 5-17 are currently pending. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/27/03. Claim 4 has been cancelled.

Claim Objections

Claims 1, 5, 6, and 15 are objected to because of the following informalities:

Claim 1 recites, "generating an *in vivo* absorption **profile**" and later recites, "based on the generated *in vivo* absorption **profiles**". Applicant is requested to correct the plural/singular relationship.

Claim 5 recites, "physiological barriers to absorption **or** a mammalian". The claims should be corrected to read "physiological barriers to absorption **of** a mammalian".

Claim 6 recites, "of the mammal system", "of said mammal system", and "segments of said mammal system". For consistency in all claims, claim 6 should be amended to recite "mammalian system".

Claim 15 recites, "**the** method of claim 2 or 6". The claim should be corrected to read, "**The** method" (capitalize the word The).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite, "generating an *in vitro* absorption profile for each of said test samples from initial dose data". It is unclear from where or what the dose data comes. Is the dose data from doses administered to the test samples, for instance or from some other source? Clarification is requested.

Claim 1 recites, "generating an in vivo absorption profile". However, there are no steps to "generate" a profile, only steps that "characterize" a profile, which is not the same as "generating". Therefore, it is unclear how this profile is generated. Clarification is requested.

Claim 1 recites a step of "selecting a desired *in vivo* absorption profile". It is unclear if this is the same absorption profile from the step of "generating a profile" or a different profile. Further, it is unclear what constitutes a "desired" profile. Clarification is requested.

Claim 1 recites, "generating a secondary compound library comprising test samples having the desired absorption profile". It is unclear as to what constitutes a "desired profile". Clarification is requested.

Claim 1 recites a final step of "based on the generated *in vivo* absorption profile...". It is unclear what this step has to do with the recited preamble of "a methods of screening a compound library". Clarification is requested.

Claim 7 recites, "wherein permeability rate data and transport mechanism data are derived". There is insufficient antecedent basis for rate data or transport mechanism data. Clarification is requested.

Claim 8 recites, "solubility rate data and dissolution rate data". There is insufficient antecedent basis in the claim for rate data in the claim. Clarification is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,996,473. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims include all of the limitations set forth in claims 1-9 of 6,996,473. '473 is drawn to a method for screening a compound library or portion thereof by absorption. The instant claims are drawn to a method for screening a compound library or portion thereof by absorption. '473 includes providing a computer-implemented phamakokinetic tool comprising an input/output system and a physiological model of a mammalian system of interest; the model comprises a selected adjustment parameter and the parameter comprises a value obtained by assigning an initial value and inputting data for a plurality of compounds into the model and running the model to generate an output; comparing the output with second data for the plurality of compounds; reducing the deviation; replacing the value with a new value; providing *in vitro* permeability and solubility data fro test samples to the tool; providing dose data; generating a

predicted *in vivo* absorption profile for the test samples; and based upon the profiles, producing a secondary compound library (claim 1).

Claims 1 and 2 of the instant application are drawn to the same limitations as set forth in claims 1, 2, and 8 of '473. The instant claims do not specifically recite "an adjustment parameter". However, it would have been prima facie obvious to one of skill in the art at the time of the invention to use the adjustment parameter of '473 in the method of the instant claims to account for the physiological barriers and determine the absorption profile. One would have been motivated to do so because the '473 specification defines the parameter for the purpose of adjustment of physiological segments (column 10).

Claims 3, 4, 5, and 7 of '473 are the same as claims 7, 8, and 12 of the instant claims.

Claim 6 of '473 is the same as claim 13 in the instant claims.

Claim 9 of '473 is the same as claim 17 in the instant application.

Conclusion

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 22, 2007
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow
Patent Examiner